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# Availability of Mammographs in Brazil

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Additional information is available at the end of the chapter

<http://dx.doi.org/10.5772/60792>

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## 1. Introduction

The Brazilian Constitution ensures in Article 196 that health is a right of every citizen and duty of the State, guaranteed through social and economic policies aimed at reducing the risk of illness and other hazards and the universal and equal access to actions and services for their promotion, protection and recovery [1]. Under the legal aspect, there is no distinction between social and economic groups, and especially concerning pathologies. This assertion is reaffirmed by Law 8080 of 1990 (Organic Law of Health) where health is declared as a fundamental human right, imposing on the State the duty to provide the necessary conditions to its full enjoyment by the preparation and implementation of economic and social policies aimed at reducing the risks of diseases and other hazards and at establishing conditions that ensure universal and equal access to actions and services for their promotion, protection and recovery [2].

As noted, the State has undertaken to draw up policies for the prevention and treatment of diseases of epidemiological interest. To be successful in such endeavor, it is therefore necessary to examine the country in its epidemiological and demographic context, so that, we can scale where there are greater demands for health care for the population. It is worth mentioning that Brazil is undergoing a profound demographic transition caused mainly by the decline in fertility that began in the mid 60s and widespread in all Brazilian regions and social strata [3].

From this perspective, it appears that the magnitude of the increase in demand for health care grows with the aging population. Taking into account this measure of population growth, there has been a considerable increase in the incidence of chronic non-communicable diseases (NCDs), becoming the largest global health problem and relating directly to the high number

of premature deaths, loss of quality of life, with high degree of limitation and disability as well as economic impacts on families, communities and society in general [4].

Estimates indicate that between 75-80% of the population at the age of 60 and over have at least one chronic condition, resulting in a contingent of 27 million in 2025 and 50 million in 2050. A similar up-scaling exercise, considering the disability, would result, in 2025, in 6.7 million older people with inevitable necessity of care and medical attention, and 12 million in 2050 [3].

Another important issue that can not be ignored, is that the development of a chronic disease in an individual of working age brings social and economic consequences since there is a decrease in productive capacity and also contributes to the increase in demand for health services. In Brazil, as in other countries, NCDs also consist of the health problem of greater magnitude and correspond to 72% of the causes of death, particularly for diseases of the circulatory system (31.3%), cancer (16.3 %), diabetes (5.2%) and chronic respiratory disease (5.8%) [4, 5].

In the wake of these considerations, it is important to note that breast cancer has too much importance in the epidemiological context of the country, because it is the type of cancer that affects more women around the world, including Brazil [6]. Mortality from breast cancer was the fifth leading cause of death for women between the ages of 30 to 39 years in Brazil and the third leading cause of death for women between the ages of 40 to 49 years. The specific rate of mortality from breast cancer for women between the ages of 40 to 49 years old was 17.2 deaths per 100,000 women [7]. In 2014, there is a prediction that occur 57,120 new cases of breast cancer in the country [8], and the increased incidence of the disease is accompanied by increased mortality, which can be mainly attributed to a delay in diagnosis and of appropriate therapy implementation [9].

Taking the limitations of the Brazilian public healthcare system, the rapid aging process points to the need to redefine the policies of this sector in order to prevent, or at least mitigate, the helpless population [3]. Still, one cannot overlook that the secondary prevention of breast cancer is based on early detection through screening of asymptomatic women and, therefore, the Ministry of Health recommends mammography every two years for women between 50 to 69 years old [7, 10]. Notwithstanding the policy proposed by the federal government to prevent breast cancer, studies have shown that there is a prevalence of women in the country who, throughout life, never had a mammogram performed both in the youngest age group (46%) and in older (49%) [11] showing that only the adoption of a policy for the prevention of disease is not enough to reach the population.

A radical shift in demand consequent to the changing age structure of the population requires the upgrading of the health system in aspects of infrastructure and human resources, as well as the development of extensive technical and methodological basis which includes a review of procedures and care protocols [3], in particular those that may contribute to the increased availability of existing mammography equipment in the country.

## 2. Problem statement

A study from 2010 stated that mammography devices acquired with public resources could cover, if rightly managed, the entire population of users in the country, however they only comply with 15 to 20% of that population. The low number of mammograms performed did not cover 20% of the equipment installed capacity [12]. From this premise it is evident the necessity of extending management actions on equipment to obtain better results within the population scope. In this regard, the National Congress of Brazil, after conducting debate on issues concerning the use of public resources in the acquisition of mammography devices and preventive detection of breast cancer, revealed through information obtained from experts in the field, that the devices were not being fully used and that early diagnosis were not being made in sufficient number. Based on these assumptions, the Congress requested the Federal Audit Court (TCU) to verify the application of federal funds in the acquisition, control and maintenance of mammography in the public health system, the private system and network of accredited units [13].

In response to the request made by the National Congress was determined to conduct a nationwide audit to diagnose the causes of low productivity of mammograms for the Brazilian population.

Already in the audit planning phase, through a cause and effect analysis factors that could possibly contribute to the limitation of performing mammograms were identified. The problems highlighted were grouped into six categories: devices, low number of mammogram requests, structure of health facilities, inputs, professionals and increased demand. These categories were then subdivided in accordance with the nature of core problems, and then grouped and arranged in a diagrammatic form shown in Figure 1.

The diagram prepared by TCU is a graphic tool in which the causes of the problem were represented by arrows, gathered to represent the effects they cause one another until their peak at the problem analysis. As can be seen, the possible causes which, together, contribute to non-attainment of mammography screening in women aged above 50 years are from diverse backgrounds, highlighting the multidisciplinary character necessary to achieve a solution, or at least minimize their effects.

To the Court of Audits, the root causes of the problem are as follows:

### 1. Equipment

#### 1.1. Inadequate geographic allocation

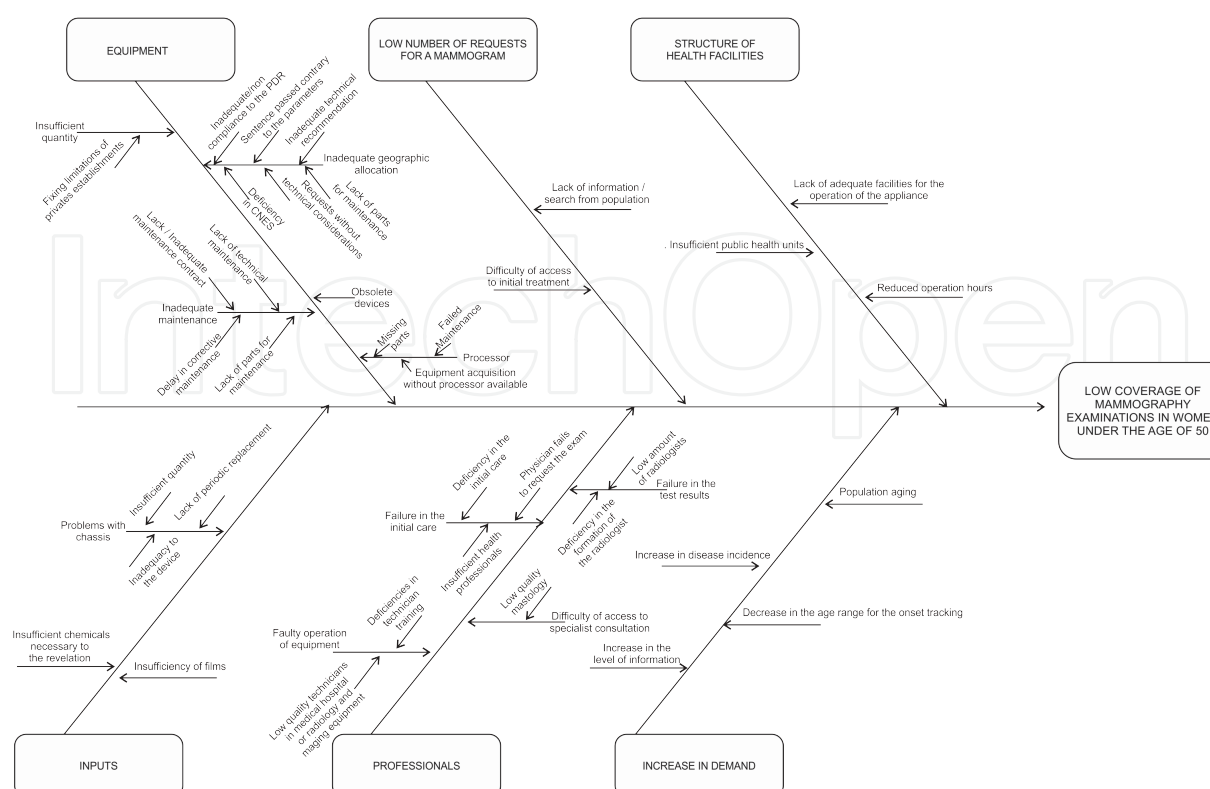
##### 1.1.1. Inadequacy/noncompliance with the PDR

##### 1.1.2. Technical opinion issued contrary to the parameters

##### 1.1.3. Inadequate technical recommendation

##### 1.1.4. Deficiency in CNES

##### 1.1.5. Requests without technical considerations



**Figure 1.** Limiting factors for mammography. Source: Adapted from ACORDAO nº 247/2010 – TCU – Plenário

### 1.1.6. Insufficient private facilities

## 1.2. Insufficient quantity

### 1.2.1. Setting forth of limitations for private facilities

## 1.3. Inadequate maintenance

### 1.3.1. Lack of maintenance technicians

### 1.3.2. Lack / Inadequate maintenance contract

### 1.3.3. Delay in corrective maintenance

### 1.3.4. Lack of maintenance parts

## 1.4. Obsolete devices

## 1.5. Processor

### 1.5.1. Lack of parts

### 1.5.2. Failed Maintenance

### 1.5.3. Equipment acquisition without processor available

## 2. Low number of requests for a mammogram

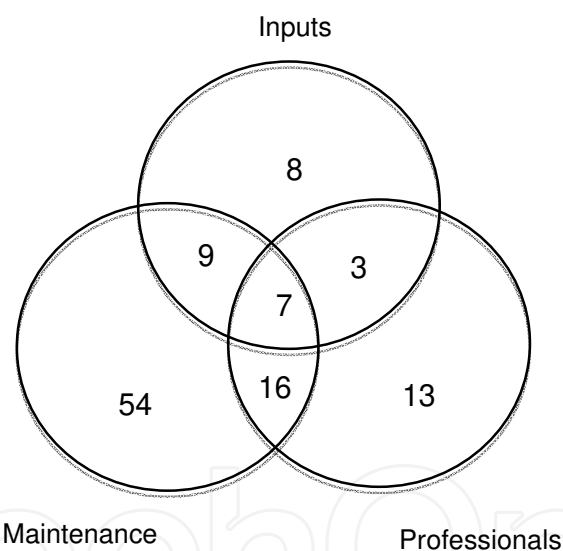
- 2.1. Lack of information / search by the population
- 2.2. Difficulty of access to initial treatment
3. Structure of health facilities
  - 3.1. Lack of adequate facilities for device operation
  - 3.2. Insufficient public health units
  - 3.3. Reduced operation hours
4. Inputs
  - 4.1. Insufficiency of films
  - 4.2. Insufficient chemicals necessary for the development
  - 4.3. Problems with chassis
    - 4.3.1. Insufficient quantity
    - 4.3.2. Lack of periodic replacement
    - 4.3.3. Inadequacy to the device
5. Professionals
  - 5.1. Difficulty of access to specialist consultation
    - 5.1.1. Low quality mastologists
  - 5.2. Failure in the test results
    - 5.2.1. Deficiency in the qualification of the radiologist
    - 5.2.2. Low amount of radiologists
  - 5.3. Failure in the initial care
    - 5.3.1. Deficiency in the initial care
    - 5.3.2. Physician fails to request the exam
    - 5.3.3. Insufficient health professionals
  - 5.4. Faulty operation of equipment
    - 5.4.1. Deficiencies in technician training
    - 5.4.2. Low quality technicians in medical hospital or radiology and imaging equipment
6. Increase in demand
  - 6.1. Increase in disease incidence
  - 6.2. Population aging
  - 6.3. Increase in the information level

#### 6.4. Decrease in the age range for the onset tracking

The audit report of the TCU showed that after the survey through questionnaires sent to health organizations selected for sampling among the six categories of root causes, three stood out by the amount of replies of healthcare facilities queried, pointing a number of flaws that interfere with the way it offers tests for the target audience. The emphasis was given to the inputs, and maintenance professionals, the latter being that concentrating the largest number of events reported by health facilities (Figure 2).

Considering the information gathered in the TCU report, the maintenance of mammography devices and development equipment is the main factor that leads to reduction or interruption of mammography, becoming a serious and frequent problem. It is observed that often there is difficulty on the part of health facilities in acquiring parts for maintenance as well as difficulties in hiring technicians to perform the services.

The TCU analysis further points that regarding the group of factors related to maintenance, were verified problems related to lack of maintenance contract, delay on part replacement, deficiency of maintenance services and processor defects [13].



**Figure 2.** Venn-Euler Diagram: Limiting factors for mammograms. Source: Adapted from ACORDAO nº 247/2010 – TCU – Plenário

As a result of lack of equipment maintenance, it was reported the existence of mammography device stopped for two years because of lack of spare parts for the old and outdated processors, without the possibility of performing maintenance and acquisition of spare parts. It has also been reported that when the obsolete processors worked, the films went out wet and the drying process was performed by means of improvised hanging lines. Some facilities reported having mammography device that had never worked because the acquisition of the mammography device was not associated with the acquisition of processor or indication how could the exams development be performed [13].



In regard to the physical infrastructure involving room shielding, refrigeration, construction or renovation works, electrical and plumbing installation, the TCU report indicates that equipment are purchased without the necessary planning related to the physical infrastructure for the equipment to be installed and its operation after delivery by the supplier. In addition, there are health centers that inform lack of sufficiency for electricity supply to the hospital, which might cause damage to the equipment during the usage phase [13].

One cannot overlook the importance of infrastructure for equipment allocation. The report notes that in a considerable amount of health units, the mammography devices acquired never became operational due to problems of structure and inadequate room shielding where the mammography device would be installed, an inadequate cooling system, need for construction works of the physical space or renovation of the existing one, inadequate electrical installations, and inadequate plumbing system. Being common for some facilities to concentrate more than one of these inadequacies.

As far as the TCU is concerned, these limitations (together or separately) resulted, to some extent, in disruption of mammography services in health facilities, poor quality of images generated, reducing the number of periods of service to the population, as well as delay in the deadline for submission of exam reports. In these conditions, retired devices are under deterioration and loss of the warranty term by lapse of time without being used.

In the country, the decisions to purchase medical equipment for health facilities are often taken with respect to a sector/department or isolated event, without giving them a multi-departmental emphasis. It is observed that, generally, the major concern of managers is focused on the acquisition and execution of works and procurement of equipment, without planning the use, maintenance and supplies [13,14]. There are reports of cases where health services eventually receive medical equipment without being in the least aware of their purchase with no prediction of qualified personnel, infrastructure and supplies to keep the device in operation [13].

Such assertions demonstrate the fact of the need to schedule the acquisition of certain equipment with the necessary infrastructure to operate it in order to provide greater availability of equipment and full use of its production capacity. In this context, actually concerning the mammography equipment purchased in the country, there is a decoupling of investment planning in the purchase of mammography equipment and further financing of production costs, without consideration at the time of the incorporation of this technology, the cost stipulated for the operation [13]. As far as the TCU is concerned, equipment is acquired without taking into consideration the necessary logistical support such as hiring of administrative and technical staff, purchase of supplies and hiring of maintenance.

Despite the clear need to implement maintenance plans, both preventive and corrective, as well as the benefits arising from them, limiting factors such as insufficient material, financial, and human resources restrict the development of these programs, especially in Brazil and, particularly, in the service public [14,15].

Another important decision to be made by the local health manager refers to the place of maintenance of the equipment, which can occur both internally - within the institution itself - as being contracted externally, especially for those equipment with the most electronic



complexity. Such decisions should be based both on the availability of material and human resources as the costs for training and maintenance of specialized personnel. In this sense, it is important that managers consider the following factors: 1) the existence of trained personnel for maintenance of every type and model of equipment; 2) existence of technical documentation relating to the equipment to receive internal maintenance; 3) existence of test and calibration equipment for the evaluation of equipment after maintenance as some types of equipment, particularly those that represent risks to the patient, require security and/or calibration tests after a preventive or corrective maintenance; 4) proximity of the manufacturer/technical representative of the equipment; and 5) the possibility of acquiring original [14] pieces.

The GM/MS Ordinance No. 1101, of June 12, 2002, establishes the parameters of health care coverage under the Unified Health System (SUS) and sets forth in its item 2.7.2, the coverage of a mammography device for every 240,000 inhabitants. At the same time, the National Cancer Institute (INCA), through technical note, has established as a production parameter of a mammography device, 6,758 mammograms/year, obtained as follows: 32 examinations /day x 22 working days/month x 12 months x 80% production capacity = 6758 mammograms/year.

Asked about the reason to establish that an equipment should produce 80% of its capacity (at the possibility of producing 100%), INCA reported that:

To calculate the capacity of a mammography device, INCA held that a professional can perform a mammogram every 15 minutes or 4 mammograms/hour, such information is obtained from professionals who perform the exam. This analysis considered only the use of a simple mammography device.

Assuming an 8-hour shift for 22 days in the month, it would be possible to perform 704 mammograms/month.

During the year would be possible to perform 8,448 mammograms/year. However, assessing that actually a device does not use 100% of its capacity, since during the year there are holidays, vacations of the professional who performs the examination, technical problems related to equipment and its maintenance, it was estimated that this “downtime” would be about 20%.

We emphasize that this parameter was built for a simple-type mammography device and that the production capacity must serve to guide the use of the equipment and should not restrict its operation, once it is locally evaluated that it is possible to go beyond it [17].

What is observed is that the INCA itself identifies two impediments for achieving the fullness of equipment operation, and maintenance personnel. Therefore, it is observed that if the equipment can provide adequate maintenance, it would also be possible to expand the examination production capacity by mammography equipment.

### 3. Application area

In the wake of TCU considerations, this case study was developed with the goal of showing among the root causes listed by TCU, which can primarily be handled by the clinical engi-

neering department of the health organization because the problems pointed out transcend several professional categories. Thus, this paper focuses dealing with those issues relating to the responsibilities of the clinical engineer, as defined by the American College of Clinical Engineering (ACCE), namely: a Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology [16].

The Clinical Engineering relates directly to what is most modern and efficient in the management of medical-hospital technologies. Taking into consideration the developmental stage reached by the science of Biomedical Engineering, associated with the increasing level of complexity of modern hospital equipment and facilities, as well as the costs involved in their acquisition and maintenance there is an increasing need of highly qualified professional training to relate to this technology to make the most of their productive capacity and increased availability. For that it is necessary that these professionals know the whole life cycle of equipment and technologies, thus being able to perform the necessary actions in order to achieve the best results with the patient.

The speed of development of new technologies is important to the clinical engineer concerning the participation in decision making processes of incorporating technologies since this professional is able to mediate the dialogue between health professionals and engineering providing crucial information for decision making regarding the selection between various emerging technologies and the infrastructure needed to support him/her. Thus, the areas of technical and scientific knowledge that should compose the list of skills of the clinical engineer pervade areas such as electrical, electronic, mechanical, civil engineering, biomedicine, sanitation, medical biology, health technologies, state of the specialized market, capacity to perform analyzes, issuance of technical opinions, drafting and project management, and training of health professionals.

The case study prepared involved a health unit with features of a large general hospital, located in the city of Brasília. An analysis of the limiting factors in the report of the TCU that can be treated by Clinical Engineering of the hospital unit was held as part of this health facility. It is worth noting that even some aspects that relate to the equipment are highly dependent on a policy for the sector, which may be the subject of further study.

#### **4. Method used**

From the reflection of the problems highlighted by the availability of equipment and mammography, were selected for analysis in this paper, the problems related to the equipment and its processors:

- a. Mammogram devices: inadequate technical recommendation, requests without technical considerations, inadequate maintenance, lack of maintenance technicians, lack/inadequacy of the maintenance contract, delay in corrective maintenance, delay in maintenance and lack of spare parts for obsolete equipment.

- b.** Processor: lack of parts, failure to maintain and purchase equipment without processor available.

Aiming to analyze in field how the processes favoring the increased availability of equipment occur, such as maintenance, a case study was conducted in a general hospital located in the city of Brasília. The hospital was opened in 1972 and has in its radiology unit facilities for providing diagnostics with equipment such as MRI, CT scanner, Pet Scan, Gamma Camera, Hemodynamics, densitometer and remote-controlled RX. The health unit concerned has in its structure a department of education and research that undertakes to provide training and education to their employees and still provides support for foreign researchers with respect to the provision of necessary permits to conduct research within the scope of the organization beyond the Research Ethics Committee (CEP). Regarding the management of medical equipment, the health unit has a contract with a company of clinical engineering, qualified to provide technical assistance on less complex equipment and also to provide advice with respect to equipment that require hiring with specialized suppliers as is the case of mammography devices.

The field research sought to investigate from multiple sources of evidence the organization of health care in the phenomenon of availability of mammography equipment. The case study concerned sought to correlate the procedures performed by the health unit with those prescribed by both the National Health Surveillance Agency (RDC 2, 2010) as prescribed by the Brazilian Association of Technical Standards through ABNT NBR 15943: 2011 - Guidelines for a management program of health service infrastructure equipment and health equipment [18].

The standard was selected because it provides minimum components required for the implementation of an equipment management plan to provide their higher availability and minimize the risks arising from the use of health technologies. The standard was designed to be applied to health services as well as companies that provide management of equipment for health services or still provide logistical support services to health services.

Another relevant aspect of the selected norm for the case study is that it specifies the minimum guidelines that involve the management of technologies such as structuring the documentation to be produced during the life cycle of the equipment, as well as the need to allocate resources in order to manage such technologies.

For the analysis of the hospital organization, the norm concerned provided a number of standard procedures where it was possible to observe its organization structure, infrastructure, personnel management, documentation management, specific requirements applied to the management of mammography, such as planning and selection, purchasing, receiving, verification and acceptance, procedure for the acceptance testing of the equipment, installation, equipment history log and archiving, training, usage, technical intervention, decommissioning and disposal and recording of adverse events related to the equipment.

The methodology selected for the analysis was the case study, which represented a way to capture the differences among the studied health units with that configuration common to the healthcare organizations surveyed by TCU [19].

The case study, of single case, the way it was conducted was described by Yin as a logical way to analyze an element that represents a critical case in testing a well-formulated theory. The theory must specify a clear set of propositions, as well as the circumstances under which the propositions are supposed to be true [20].

Upon confirming, contesting or extending the theory, there must be a unique case satisfying all conditions to test the theory. The only case can then be used to determine whether the propositions of a theory is correct or if some other set of alternative explanations may be more relevant.

Considering the need to collect data directly in the health unit under analysis, the research had characteristics of a field study involving descriptive and exploratory aspects. The descriptive aspects consisted in empirical research whose primary purpose was the design and analysis of the characteristics of the health service and evaluation of internal processes adopted culminating with the possibility of increased availability of mammography equipment.

Regarding the exploratory characteristics, these were evidenced in the research itself, performed in the field, on the premises of the health unit. The aim was to formulate questions with employees of the health unit, with three purposes: developing hypotheses, increasing the familiarity of the researcher with the environment, and also clarifying of theoretical concepts. The study methodology was appropriate for the research, because when entering the halls of the health unit to conduct the research, it was possible to understand environmental issues such as organizational structure available, forms of interaction among units and how the hierarchy of the processes described in the study was established.

Delimitation of the study: a case study of single case, exploratory-descriptive nature combined, performed in a hospital located in the city of Brasília, DF, classified as a general hospital, financed by public funds from the Union on the management of mammography devices on the basis of ANVISA RDC No. 2 of 2010 [21] and ABNT NBR 15943: 2011. The selection criteria of the sample was a non-probabilistic, purposive sampling, with the election of a hospital located in the city of Brasília, DF.

For the research purposes, this type of sampling was efficient, where was up to the researcher, to deal appropriately with his/her limitations, in order to provide the best way to replicate the study in other health units of the same size and specifications without disregard those factors that impose special conditions for replication, such as environmental, social, cultural ones.

## 5. Results

The health service in response to the determination of the National Health Surveillance Agency (ANVISA) implemented in its unit a Plan of Management Technologies in Health, as determined by RDC 2, of 2010 of ANVISA. In this sense, a firm of clinical engineering specialized in creating and implementing the referred plan was hired, acting as consultant of the Hospital Board in issues related to the acquisition and incorporation of new technologies. For a perfect execution of the procedures, a contract, which sets out the rights and duties of both parties,

indicators to measure the quality of services, provided and the payment, was signed between the service provider and the hospital. If the contracted party does not reach the quality level desired and stated in the contract, there is on the part of the health care organization, ways to decrease the amount to be paid, so that the service provider receives as per delivered quality.

The contract signed with the clinical engineering company aims to establish minimum actions regarding care for the health technologies through management actions and advisory services or specialized consulting. Thus, the institution aims to meet what is being set forth by Resolution RDC No. 2 of ANVISA, in order to ensure the implementation of measures to ensure traceability, quality, efficacy, effectiveness and safety of health technologies.

Among the actions enforced by the contract, there is a focus on management (i.e. receipt, alienation /disposal, installation, uninstallation and operability.), corrective and preventive maintenance, calibration and specialized consulting in technology (infrastructure and equipment).

Therefore, it is intended to achieve on a continuous and sustainable basis the quality of care for the treatment and hospitalization of the target audience of health institution, requiring general and specialized medical and surgical treatment. Another aspect to be considered is to optimize the application of resources for the maintenance and use of the technology park, aiming to achieve excellence in the management of medical-hospital equipment, increase in safety and reliability of medical equipment, their facilities, infrastructure and quality of care.

In order to reach the expected results with the hiring company, the hospital unit undertook to technically qualify the company that should execute the contract. For that, the technical issues that should be covered by the company were incorporated into the contract:

Registration of the company, with the Regional Council of Engineering and Architecture (CREA), in the areas of electrical, mechanical and civil engineering (or architecture), indicated by the technician responsible for the contract performance.

Requirement that the company have in its staff, an engineer with postgraduation (specialization, masters or PhD) in Biomedical Engineering or Clinical Engineering to supervise the activities of the company, other than the Registration of Technical Responsibility (ART) for services object of the present specifications, on behalf of the engineer qualified for this purpose, belonging to the permanent technical staff of the company.

Activities of equipment management are the responsibility of a public servant appointed by the Director of the Health Unit as a contract manager with the outsourced company. His/her professional duties and responsibilities are formally described (in the mammography device maintenance contract), which provides this servant with the capacity to engage with the work to be done on a supported basis by the organization.

For these professionals, trainings that involve the knowledge of management actions including knowledge of the law applied to the issue are performed. The trainings are conducted by a dedicated department, and the content taught is directed as activities developed by professionals with a record of their achievement and participation of these professionals.



The clinical engineering company hired to manage the technology park keeps writing record of the activities described in the Plan of Technology Management in Health with all Standard Operating Procedures (POPs) described and approved by the contract manager.

With regards to the mechanisms established by the health service to generate, store and make available technical and managerial information about the equipment and the procedures used by the health service, there is a systematic documented and enforced by the people in charge, safeguarding that all records are performed manually in books and other paper documents. These records document all the events related to incidents and equipment failures, technical calls, scheduled visits of technicians in equipment maintenance, procedures, replacement of parts or pieces of equipment. All activities recorded in the books and documents are signed and dated by those who performed the procedure.

In the radiology unit, all of mammography documentation, including their manuals, manufacturer's guidelines, record of calibrations and procedures performed at the frequency established by the equipment manufacturer are grouped and stored.

The resources required to implement the planning of technology management, derive from a budget planning prepared by the management of the hospital organization, taking into account the balance between the needs of the unit and resources availability provided by the Union.

The health unit had until then in its premises an analog mammography equipment and effected its technological upgrading to a digital equipment. Feasibility studies were completed, taking into account the demand for mammography, production capacity of the equipment, resources required for incorporation of the digital equipment, as well as the need to adapt to the existing machine to accommodate the new environment without compromising provision of services to the population served.

In the selection phase of the technology to be incorporated, the health service established technical criteria to be met by potential suppliers candidates to sell the equipment. The prominence given by the health unit refers to the regularity of both the equipment as its suppliers with the body of sanitary control of the country, as well as with the validity of the importation (if it were produced in the country) of all parts of the equipment.

The procurement of equipment is performed by a bidding process complying with the provisions of Law 8,666 dated June 21, 1993 [22]. The hospital maintains a purchase unit by bidding procedure, in which all processes and procedures related to the procurement are recorded. Further, in compliance with the procurement legislation, all acts are published in the official union gazette, thus giving transparency as regards the spending of public funds.

After the procurement procedures, already during the receipt of the equipment, the health service has established criteria for receiving equipment involving analysis: (1) of the technical specifications of the equipment (comparison between what is being delivered with what has been specified for acquisition); (2) regarding evidence of the regularization of equipment with ANVISA; (3) tax documents and other manuals (required to be written in the vernacular language).



The stage of receipt and acceptance of mammography comprises: (1) receipt of the equipment parts in a box (health unit); (2) opening and checking of contents of the boxes (supplier); (3) installation of equipment (supplier); (4) checking of specifications (provider and health unit); (5) acceptance testing (supplier and health unit), and (6) training of users (provider and health unit). All stages of receipt are documented, signed and dated by the participating parties.

The installation of mammography device involved analysis of the infrastructure recommended both by the manufacturer as health monitoring and nuclear energy bodies. Testing and equipment acceptance procedures involve tests that must be met. If during the tests and trials phase nonconformities are detected with the object originally described, the equipment should be listed as unfit for use until the inconsistency has not been remedied.

The acceptance tests are formalized in the mammography device acquisition document being conducted jointly between the health unit and the supplier involving test actions and adaptation of procedures documented in the health unit so that there is compliance with these applicable technical standards for the equipment, safety instructions issued by the manufacturer and procedures required to ensure the increased equipment working life. During the testing execution phase, the equipment is not available for use with patients until the equipment acceptance certificate is issued jointly by the contract manager, technicians responsible for the use and provider.

Participate in the acceptance testing: (a) the user of equipment; (b) the person responsible for approving the payment of the equipment; (c) the person responsible for managing assets; and (d) the person responsible for equipment operators' training.

After the acceptance testing phase, trainings are initiated with users and technicians who will operate the mammography device. The equipment supplier shall provide the necessary training to ensure that each service agent is able to perform his/her activities. The training performed aims at individually qualifying each employee involved in the use and availability of equipment, involving even the administrative activities. The training content was been previously discussed between the provider and the health unit, including training regarding security standards in legal and normative acts.

The training sessions provided by the supplier were documented and signed by the participants. The documentation involves from all approached syllabus, attendance record, evaluation of the effectiveness of training and provision for dealing with doubts and questions.

After the training phase, only skilled professionals are allowed to handle the mammography device, implying a greater patient safety. The radiology technician before operating the equipment performs configuration tests and records the values obtained in a proper book in order to ensure traceability procedures. As it is an ionizing radiation emitting equipment, all procedures follow the provisions of the National Council for Nuclear Energy (CNEN).

The mammography device in use at the health unit was purchased less than two years and, therefore, it is covered by the manufacturer's warranty contract. Thus, the services of preventive and corrective maintenance are scheduled by the equipment supplier, providing a greater equipment availability.

Despite the manufacturer's warranty coverage, the health service has an equipment maintenance policy already documented comprising: (a) the metrological traceability of the equipment; (b) inspections, testing, maintenance, adjustment and calibration of the equipment. All technical interventions made by the equipment supplier are documented in the historical record of the equipment.

The hospital established a systematic approach to preventive and corrective maintenance of the facilities and mammography equipment, being documented on physical media, without a computerized system for recording maintenance actions.

In case of need to perform corrective maintenance procedures, the equipment is then deactivated and the structure required for the maintenance to be performed with the provision of appropriate equipment and tools to do so is installed in the machine room itself. To this end, the health unit maintains a flow of procedures since the perception of an equipment failure by the user until its solution, by the service provider. The systematic approach developed by the health unit encompasses recording failure in a proper form, call record, deadline for implementation of services and reservations regarding the possibility of acquiring pieces in national territory or if imported (which affects the execution time of services).

The space dedicated for use by maintenance staff is sized and compatible with the activities developed, and maintained in good repair, cleaning and hygiene status, protection against the entry of insects and rodents, featuring electrical installations, lighting and air conditioning systems required for health maintenance equipment and the activities performed, according to the manufacturer's recommendation, and it is even possible to track the effect of environmental temperature on the mammography device.

All documents relating to the technical intervention are subsequently attached to the historical documents of the equipment, producing a medical chart where all phases of equipment life cycle are reported.

The person in charge of the health service follows up the interventions and preventive maintenance procedures performed by the provider's technicians based on standard records, aiming to analyze that the actions required to verify that the equipment is in working condition and according to their specifications.

With respect to the mammography device installed at health unit, there are no reports of adverse events related to the equipment. The patients reported some discomfort, resulting from the pressure needed to be done on the breasts during the exam. The administration of the radiology unit considers that this discomfort is common, and there is no need to notify both the manufacturer and the National Health Surveillance System. The procedures for investigating adverse events are described in the unit, should they occur.

The health unit maintains a historical record of mammography equipment, comprising: (a) the identification of the unit at the health facility where the equipment is allocated; (b) professional appointed by the health service responsible for the equipment use; (c) history of equipment failures; (d) documented history of problems and incidents related to adverse events caused, or potentially caused by equipment failures; (e) documentation of technical interventions on the equipment.

Historical records of equipment are filed in the radiology unit itself, under the safeguard of the person responsible for the unit.

Prior to the acquisition of mammography device in use, there was another analog machine installed at the health unit. This machine was donated to another health unit because it was still able to be used. This fact prevented the hospital to be concerned about the disposal of the equipment, so it was enough that the document was transferred to another health facility. Care involved in this phase focused on how to disassemble the equipment in use until then without damaging it and be mounted on the receiving unit to maintain its usability.

It is worth noting that in the health unit analyzed, the mammography equipment is available since its installation, having stopped just in time for the scheduled maintenance. The maximum wait time allowed for completion of a mammogram is seven days after its appointment, and the unit has realistically fulfilled this goal, and so there are no queues for the exam by the target audience of the hospital.

## 6. Further research

The research performed focused on unraveling the events related to the technology management through clinical engineering. It is extremely important to emphasize that based on the root causes of the problem reported by the TCU report it would still be necessary to consider other aspects that influence the low incidence of mammograms and the consequent early diagnosis of breast cancer in the population.

Accordingly, future studies that can be used throughout the life cycle of the equipment are recommended, involving preliminary technical studies that may indicate in addition to the need of equipment focused on the growing demand for mammograms, the manner to improve their geographic distribution in a country of continental dimensions like Brazil. Technical issues involving the purchase of mammography equipment are coupled with factors such as availability of technical and administrative personnel in a sufficient amount, qualified and motivated.

Studies for expanding the supply of basic inputs such as films and reagents required for their development or installation of equipment that can scan images in order to minimize the need for films, including having an effect on the environment. Moreover, another issue to be analyzed and studied supports the best way to provide information to the public about the importance of the exams within the minimum intervals recommended by the Ministry of Health.

## 7. Conclusion

Brazil is a country of continental dimensions and problems of the same magnitude. Within the health sector, the problems related to health services management (in all its variations) show

that there is a significant gap between what is done by the State to provide health care for the population and their quality expectations.

It is already known by the State that the demographic and epidemiological transitions that the country is subjected to will be reflected across the health system in a few years, because with the aging population, the burden of non-communicable chronic diseases tends to increase, which is different in countries with a predominantly young population.

In terms of the legal and political apparatus existing in the country supporting the creation of health programs, whose purpose is to increase of quality of life for the population, the problems reported by the TCU in relation to the low productivity of mammograms are presented only as a small link in a chain of problems.

Most of these problems approached in the report, are associated with the absence of prior planning for the purchase and installation of mammography equipment. Notwithstanding this fact, the case study revealed that it is possible to reach a condition of increased availability of mammography equipment, with the participation of the Clinical Engineering as part of the decision making and management processes.

In a process of analysis and correction of problems, the Clinical Engineering within its competence scope, would act on the equipment management, providing both the planning of the necessary infrastructure and the equipment support after its purchase. The direct and indirect benefits of the action of the Clinical engineering can be seen through increased safety for patients and technical staff because, as processes and procedures for maintenance of mammography devices, as well as their periodic calibrations and measurements are there was a direct reflection on the nonoccurrence of adverse events arising from the use of mammography device.

Another relevant aspect is the fact that the increased availability of mammography devices, has direct effects on the economy of the health facility, because the presence of a non-effective equipment imposes upon this facility the cost of obsolescence and technological gap without the provision of its direct purpose, namely, the ability to provide early breast cancer diagnosis. The possibility of the occurrence of this condition is even more serious, whereas the facility would have means of diagnosing it early if the equipment was not out of operation.

Regarding the application of standardized procedures by ABNT NBR 15943: 2011, their effects are measured directly on the availability of mammography devices, since the standard is concerned to provide important steps to be followed throughout the organization, taking care of the equipment life cycle from the planning phase of its acquisition to its final disposal.

During the research at the health care facility, we observed the attention given by professionals to meet the guidelines set forth in the standard from the initial conception of the acquisition of the mammography device, disabling of the equipment that was in use, the new equipment installation, analysis, issuing of reports and testing, technical staff training, provision of maintenance and support by the clinical engineering. All these factors were reflected in the availability of the equipment in full time, considering the low waiting time on the part of the target audience to achieve the performance of a mammogram.

## Nomenclature

**Competent sanitary authority:** an authority who is responsible, in his/her territorial demarcation, for the implementation of appropriate sanitary measures in accordance with the laws and regulations prevailing in the national territory, international treaties and other acts, of which Brazil is a signatory.

**Calibration:** a set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, values represented by a material measure or a reference material and the corresponding values of the quantities set forth by standards.

**Availability:** capacity of an item to be able to perform a certain function at a given time or during a given time interval, taking into account the combined aspects of its reliability, maintainability and maintenance support, assuming that the required external resources are ensured.

**Health equipment:** a set of devices and machines, parts and accessories used by a health care setting where diagnosis actions, therapy and monitoring are developed. Shall be considered health equipment those support, infrastructure, and general medical care devices.

**Medical-care equipment:** equipment or system, including their accessories and parts, of usage or medical, dental or laboratory application, used directly or indirectly for diagnosis, therapy and monitoring in health care of the population, and which do not use pharmacological, immunological or metabolic means to perform their main function in humans, whereas being able to be assisted in their functions by such means.

**Adverse events:** damage to health caused to a patient or user due to the use of a product subject to sanitary surveillance regime, whereas its use is carried out under conditions and parameters prescribed by the manufacturer.

**Health technology management:** a set of management procedures planned and implemented from scientific and technical, normative and legal bases in order to ensure traceability, quality, efficacy, effectiveness, safety and in some cases the performance of health technologies used in the provision of health services. It covers every step of management, from planning and admission into the health unit until its disposal, in order to protect workers, the preservation of public health and the environment and patient safety.

**Maintenance:** a combination of all technical and administrative actions, including supervision to maintain or replace an item in a state in which it can perform a required function.

**Management Plan:** a document indicating and describing the criteria established by the health facility for performing the management steps of different health technologies subject to health inspection and supervision from planning and admission into the health care setting, until its use in health and disposal services.

**Traceability:** the capacity to trace the history, application or location of an item by means of previously recorded information.



## Acknowledgements

Special thanks to the Laboratory of Health Informatics (LIS) at the University of Brasília, at Gama (FGA), for providing an important space for learning and information exchange between teachers and students. Thanks are intended for professionals in the health care unit who welcomed us carefully and dedicated their precious time to provide the requested information.

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